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MEDTRONIC, INC.
710 MEDTRONIC PARK
MINNEAPOLIS, MN 55432-9924

EXAMINER

GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/813,307

Applicant(s)

DINSMOOR ET AL.

Examiner

Andrew M. Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 6-16, 33-40 and 48-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 17-31 and 41-47 is/are rejected.
- 7) ☒ Claim(s) 4, 5 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 11/16/2006.
2. In the reply, the Applicant amended claims 1, 18-23, and 29.
3. The objection to the drawings has been withdrawn pursuant to 37 CFR 1.83(a).
4. The Applicant did not submit or provide arguments against the rejections for obviousness-type double patenting in the previous office action. Thus, the rejections are maintained. Furthermore, the Examiner notes that the rejection to US Pat No 6689056 is not a provisional application as mentioned (see Remarks, pg 17, paragraph 1 and 6) because the reference is a US Pat.
5. Claims 1-5, 17-32, and 41-47 remain pending.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 17-18, 25-28, 29, 41, 43, 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Silverstein et al, hereafter "Silverstein", (5247938). In reference to

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independent claim 1 and 29, Silverstein discloses the apparatus and method for attaching and detaching a medical device (col 1, ln 66-col 2, ln 8; Fig 1-3, 9) for placement within a body lumen of a patient, the device comprising: a device housing (48) sized for introduction into and residence of the medical device completely within the body lumen (see Response to Arguments below); a fixation mechanism (col 4, lns 43-45; col 6, ln 1-15) to attach the device housing to a surface within the body lumen; a detachment mechanism (col 4, lns 43-45; col 6, lns 1-15) to selectively detach the device housing from the surface of the body lumen.

8. In reference to claim 17 and 41 (see col 6, lns 1-15 and the Examiner notes that a source of suction is well known to have a power source); for claim 18 (see (138)); for claim 25 and 46 (see col 4, lns 37-38); for claims 26 and 27 (see col 3, lns 43-48); for claim 43 (see col 6, lns 1-15 and the Examiner notes that when the controller of the source of suction, which is external to the body lumen, is turned off, the detachment mechanism is activated); for claim 28 and 47 (see col 3, lns 42-47).

9. Claims 1-3, 18-20, 24-27, 29-31, 45-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Kilcoyne et al (6689056).

The applied reference has a common invention with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

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the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In reference to independent claims 1 and 29, Kilcoyne et al discloses the apparatus and method for attaching and detaching a medical device (Figs 8-11) for placement within a body lumen of a patient, the device comprising: a device housing (18) sized for introduction into and residence completely within the body lumen; a fixation mechanism (Figs 8-11) to attach the device housing to a surface within the body lumen; a detachment mechanism (col 9, lns 55-col 10, ln 4) to selectively detach the device housing from the surface of the body lumen (see Response to Arguments).

In reference to claim 2 and 30 (see (124); Fig 16); for claim 3 and 31 (see col 10, lns 24-26); for claim 18 (see col 7, lns 50-53; col 7, ln 66-col 8, ln 15); for claim 19 (see col 7, ln 66-col 8, ln 15); for claim 20 (see col 9, lns 61-col 10, lns 3; col 11, ln 54-56; where the Examiner has interpreted the controller to be the biodegradable material, the control signal to be the psychological response by the human body to the material to begin to degrade the attachment mechanism; thus, turning the attachment mechanism into the detachment mechanism); for claim 24-25 and 45 (see col 5, ln 63-col 6, ln 4); for claim 26-27 and 46 (see col 7, ln 17-38).

10. Claims 1-3, 24-31, 45-47 rejected under 35 U.S.C. 102(e) as being anticipated by Colliou et al (7020531).

11. In reference to independent claims 1 and 29, Colliou et al discloses the apparatus and method for attaching and detaching a medical device (Figs 1-13b) for

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placement within a body lumen of a patient, the device comprising: a device housing (520) sized for introduction into and residence completely within the body lumen; a fixation mechanism (524, 564; Figs 1-13b) to attach the device housing to a surface within the body lumen; a detachment mechanism (5224, 564, Figs 1-13b; col 5, Ins 36-42) to selectively detach the device housing from the surface of the body lumen.

12. In reference to claim 2 and 30 (see 522); for claim 3 and 31 (528; Summary); claim 24-25 and 45 (see Figs 1-13b, Summary); for claim 26-27 and 46 (see Figs 1-13b, Summary – ie col 7, Ins 21-37); for claims 28 and 47 (see Figs 1-13b; Summary – ie col 7, Ins 55-65).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 21-23, 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al. Kilcoyne et al discloses the invention substantially as claimed except for expressly disclose a telemetry circuit, telemetry signal, magnetic circuit, external magnetic source, inductive coupling circuit, and external inductive element. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a telemetry circuit, telemetry signal, magnetic circuit, external magnetic source, inductive coupling circuit, and

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external inductive element because the Applicant has not disclosed that having a telemetry circuit, telemetry signal, magnetic circuit, external magnetic source, inductive coupling circuit, and external inductive element provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the detector and control signal of Kilcoyne et al because it performs substantially the same function of releasing the device from the body lumen in a user controlled manner. Therefore, it would have been an obvious matter of design choice to modify the control mechanism of the detachment mechanism to obtain the invention as specified in claims 21-23.

15. Claims 21 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al in view of Christopherson et al (6021352). Kilcoyne et al discloses the invention substantially as claimed except for expressly disclosing that the detector includes a telemetry circuit to receive the control signal as a telemetry signal from an external controller. Christopherson et al teaches that it is known to have a telemetry circuit (440; Fig 18; 20D) for the purpose of controlling the device external of the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the detector as taught by Kilcoyne et al with the telemetry circuit as taught by Christopherson et al for the purpose of controlling the device external of the body.

16. Claim 22 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al in view of Cimochoowski et al (5967986). Kilcoyne et al discloses the

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invention substantially as claimed except for expressly disclosing that the controller includes a magnetic circuit to sense the presence of an external magnetic source as the control signal. Cimochoowski et al teaches that it is known to have the detector includes a magnetic circuit (110; Fig 10) to sense the presence of an external magnetic source (94; Fig 10) as the control signal for the purpose of controlling the device external of the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the controller as taught by Kilcoyne with the magnetic circuit and external magnetic source as taught by Cimochoowski et al for the purpose of controlling the device external of the body.

17. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al in view of Imran et al (6535764). Kilcoyne et al discloses the invention substantially as claimed except for expressly disclosing that the controller includes an inductive coupling circuit to generate power from an inductive element external to the body lumen and thereby activate the detachment mechanism. Imran et al teaches that it is known to have the detector includes an inductive coupling circuit to generate power from an inductive element external to the body lumen and thereby activate the detachment mechanism (col 22, lns 8-30; col 23, lns 20-33) for the purpose of controlling the device external of the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the controller as taught by Kilcoyne et al with the inductive coupling circuit and inductive element external to the body lumen as taught by Imran et al for the purpose of controlling the device external of the body.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-3, 16, 18-19, 24-27, 29-31, 45-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6689056. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the US Pat No 6689056. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application. It has been held that the generic invention is anticipated by the species.

20. Claims 1, 18, 24-27, 29, 45-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-17, 62-87 of copending Application No. 10/833776. Although the conflicting claims are

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not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending application. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application. It has been held that the generic invention is anticipated by the species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Claims 1-3, 18, 24-27, 29-31, 45, 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-11, 13-16, 55-58, 61-66 of copending Application No. 10/687296. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending application. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application. It has been held that the generic invention is anticipated by the species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 1-3, 18, 19, 24-27, 29-31, 45, 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 55-58, 66, 69, 71, 73 of copending Application No. 10/896533. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending application.

Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application. It has been held that the generic invention is anticipated by the species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claims 1-3, 18, 24-31, 45, 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53 of copending Application No. 10/835425. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending application. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application. It has been held that the generic invention is anticipated by the species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

24. Applicant's arguments with respect to claims 1-5, 17-32, 41-47 have been considered but are moot in view of the new ground(s) of rejection.

25. Applicant's arguments filed 11/16/2006 have been fully considered but they are not persuasive.

26. The Applicant argued that:

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- i. Silverstein et al fails device is not sized for residence completely within the body lumen. (Remarks, pg 13, paragraph 5)
- ii. Silverstein et al fails to include a controlled detachment mechanism of the medical device. Furthermore, biodegradable materials cannot be controlled once in the patient so they do not anticipate a controlled detachment mechanism. (Remarks, pg 14, paragraph 2)
- iii. Kilcoyne et al does not teach or suggest a controlled detachment mechanism because dissolvable materials are subject to the environment and any changes that may occur so that the detachment mechanism is at the mercy of the surrounding environment in order to detach from the esophagus, thus the clip cannot be a controlled detachment mechanism. (Remarks, pg 15, paragraph 1).

27. In response to applicant's argument (i) that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the device) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The Examiner notes that the Applicant merely recites that the device housing is sized for introduction into and residence completely within the body lumen. The Applicant does not recite that the entire medical device resides completely within the body lumen; consequently, the device housing (48, Fig 3) still resides completely within the body lumen and anticipates the claim. Furthermore, in regards to claim 29, the Examiner

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notes that the recited limitation of "wherein the medical device is sized for residence completely within the body lumen" does not preclude an attachment (72) to the medical device (48) being attached and extending from the medical device to an position external from the body lumen. The recitation of the medical device as claimed does not preclude that the entire apparatus is located and resides within the body lumen. The Examiner suggests clarifying the limitation to define that the medical device after implantation resides completely within the body lumen and is not physically connected to an apparatus external from the body lumen.

28. In response to applicant's argument (ii) and (iii), the Examiner disagrees with the Applicant's interpretation of the claim language. First, Silverstein et al does disclose a controlled detachment mechanism being a suction mechanism that controllably applies suction force to attach the device housing to the surface of the body lumen and detaches by releasing the suction force to detach the detachment mechanism from the body lumen. That is a controlled detachment mechanism. Secondly, biodegradable materials forming clips or sutures securing the body housing of Silverstein et al of Kilcoyne et al to the body lumen are a controlled detachment mechanism for selectively detaching the device housing from the surface of a body lumen. By definition, biodegradable materials have rates of degradation that can be controlled to biodegrade in the body over a specified time. It is well known that different biodegradable materials degrade in the body over different time periods. Thus, one of ordinary skill in the art can choose a biodegradable material to secure the body housing over a specified time period before dissolving to act as a controlled detachment mechanism. The

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detachment mechanism is controlled because the user can specify when the detachment will occur through the rate of degradation of the biodegradable material in the body. Thus, the rejections are maintained.

Allowable Subject Matter

29. Claims 4-5 and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571)

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272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert



NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700